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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/416,779      | 10/13/1999  | FRANCO P. PREPARATA  | BUV-003.01          | 6623             |

28120 7590 04/05/2004

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EXAMINER

CLOW, LORI A

ART UNIT PAPER NUMBER

1631

DATE MAILED: 04/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/416,779

Applicant(s)

PREPARATA ET AL.

Examiner

Lori A. Clow, Ph.D.

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-8,10-12 and 20-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7,8,10-12,23-26,28 and 29 is/are allowed.
- 6) ☒ Claim(s) 1-4,6,20-22 and 27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### DETAILED ACTION

Applicant's arguments, filed 28 November 2003, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-4, 6-8, 10-12, and 20-29 are currently pending.

The art rejection under 35 USC 102 over US 6,440,677 has been withdrawn. In light of the withdrawal, Applicant's arguments pertaining to US 6,440,677 are moot.

### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 20, 22, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Candrian et al. (Applied and Environmental Microbiology (1991) April, pages 955-961). ***This is a new grounds of rejection.***

Candrian et al. teach the use of inosine-containing oligonucleotide primers for enzymatic amplification of different alleles. Instant claim 1 is drawn to a nucleic acid probe comprising a sequence of universal and designate nucleotides ordered in a pattern. The pattern must comprise a first string of universal nucleotides followed by a second string of universal nucleotides followed by a segment. The first string and second string comprise two or more consecutive

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universal nucleotides and the first segment and second segment comprise a designate nucleotide. Candrian et al. teach a primer comprising the following pattern of universal and designate nucleotides which meet the limitations of the claim:

5'-**TTITTCTGTATTITCTTTIICHICTTTIITCAG**-3'.

Further, claims 3 and 4 are also anticipated by the teaching of Candrian et al, in that a plurality of instances of the pattern exists and designate nucleotides are bound to the end of the sequence (page 957, Figure 1).

Claims 20, 22 and 27 are anticipated by Candrian et al. in that the pattern comprises a first string of universal and/or nucleotide analogs, followed by a first segment, and a second string of universal and/or nucleotide analogs followed by a second segment; the first and second strings comprise two or more consecutive universal nucleotides and/or nucleotide analogs; and the first and second segments comprise at least one designate nucleotide and/or nucleotide analog. Further, at least two contiguous designate nucleotides and/or nucleotide analogs are bound to an end of the sequence (claim 22) and the designate nucleotide and/or nucleotide analog comprises a purine or pyrimidine base (claim 27).

### **Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6, 20-22, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Candrian et al. (Applied and Environmental Microbiology (1991) April, pages 955-961), in view of Bergstrom et al. (Nucleic Acid Research (1997) Vol. 25, pages 1935-1942).

Candrian et al. teach the use of inosine-containing oligonucleotide primers for enzymatic amplification of different alleles. Instant claim 1 is drawn to a nucleic acid probe comprising a sequence of universal and designate nucleotides ordered in a pattern. The pattern must comprise a first string of universal nucleotides followed by a second string of universal nucleotides followed by a segment. The first string and second string comprise two or more consecutive universal nucleotides and the first segment and second segment comprise a designate nucleotide.

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Candrian et al. teach a primer comprising the following pattern of universal and designate nucleotides which meet the limitations of the claim:

5'-**TTITTCTGTATTITCTTT**II**CTTT**II**TCAG**-3'.

Further, claims 3 and 4 are also anticipated by the teaching of Candrian et al, in that a plurality of instances of the pattern exists and designate nucleotides are bound to the end of the sequence (page 957, Figure 1).

Claims 20, 22 and 27 are anticipated by Candrian et al. in that the pattern comprises a first string of universal and/or nucleotide analogs, followed by a first segment, and a second string of universal and/or nucleotide analogs followed by a second segment; the first and second strings comprise two or more consecutive universal nucleotides and/or nucleotide analogs; and the first and second segments comprise at least one designate nucleotide and/or nucleotide analog. Further, at least two contiguous designate nucleotides and/or nucleotide analogs are bound to an end of the sequence (claim 22) and the designate nucleotide and/or nucleotide analog comprises a purine or pyrimidine base (claim 27).

Candrian et al. do not teach the use of 5-nitorindole or 3-nitropyrrole nucleotide analogs. However, Bergstrom et al. do teach incorporation of these analogs into oligonucleotides. It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to utilize 5-nitroindole and 3-nitropyrrole in the primers designed by Candrian et al. One would be motivated to do so because Bergstrom et al. indicate that in their comparison studies of 5-nitroindole and 3-nitropyrrole to other nucleoside analogs that 5-nitroindole and 3-nitropyrrole are exceptionally non-discriminating base paring partners (page 1942, conclusion).

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The study was undertaken to specifically guide the development of more effective universal spacers (page 1935, column 2).

Claims 7, 8, 10-12, 23-26, and 28-29 are allowable.

### **Inquiries**

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

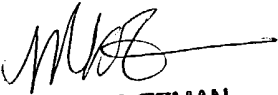
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (571) 272-0549.

April 2, 2004

Lori A. Clow, Ph.D.

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*Lori A. Clow*

  
**MARY K. ZEMAN**  
**PRIMARY EXAMINER**  
AU 1631  
4/2/04